

**TESTIMONY OF  
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Chairman Grassley, Senator Breaux, distinguished Committee members, thank you for inviting us to discuss our progress in improving the quality of care in Medicare's End Stage Renal Disease (ESRD) program. We would also like to thank the General Accounting Office and HHS Inspector General for their assessments and assistance in this area, as well.

We are working diligently, in partnership with the dialysis community, to improve the quality of care provided to Medicare End Stage Renal Disease beneficiaries, and we have had measurable success. Between 1993 and 1998 the percentage of ESRD patients with adequate red blood cell (hematocrit) levels increased from 46 to 83 percent, while the percentage of patients receiving adequate dialysis increased from 43 to 74 percent. And, between 1990 and 1997, the overall one year mortality rates for dialysis patients declined from 24.9 deaths per 100 patient years to 22.8.

We are committed to working with States and the End Stage Renal Disease Networks to make further improvements and target weak performing dialysis facilities. We are testing more advanced measurements of the quality of care provided in dialysis centers. We are developing new rules to strengthen quality requirements for dialysis centers. And we are developing facility-specific data that will help consumers make informed choices, help facilities identify areas in which they need to make improvements, and help surveyors target oversight efforts.

We also want to decrease the time between surveys of dialysis facilities, from every six years to every three years, so we can better monitor the quality of care. To do so, the President's fiscal 2001 budget would increase funding for surveys from \$2.2 million to \$6.3 million. And we look forward to working with you to secure this much-needed revenue.

We also want to increase payment for outpatient dialysis, which until this year had not been updated since 1991. For the past several years, the Medicare Payment Advisory Commission (MedPAC) has recommended updating the rates to reflect the increasing acuity of patients and cost of services. The Balanced Budget Refinement Act of 1999 went part of the way by increasing the rates 1.2 percent in 2000 and another 1.2 percent in 2001. The President is proposing to fully comply with MedPAC recommendations and increase the rates another 1.2 percent for 2001. We look forward to working with you to secure this funding, as well.

***BACKGROUND***

The Medicare statute was amended in 1972 to specifically authorize coverage for individuals with diabetes, hypertension or other diseases that result in severe impairment of kidney function known as ESRD, beginning in 1973. Since then, Medicare has paid for some \$126 billion worth of services for a total of more than one million ESRD patients. The number of patients served has grown steadily and there are now over 300,000 Medicare ESRD beneficiaries. The program is projected to pay out \$15.3 billion in ESRD-related benefits this year, some \$5 billion of which will go to nearly 4,000 dialysis providers, with 58,248 approved outpatient stations providing dialysis treatment.

The Medicare ESRD benefit specifically includes coverage for kidney transplantation. Mortality rates are 50 percent lower for ESRD patients who receive a kidney transplant versus those who remain on dialysis, according to the United States Renal Data System. The 1-year graft survival rate for living

donor transplants increased from 88.8 percent in 1988 to 93.9 percent in 1996, according to a recent paper in the New England Journal of Medicine. For cadaveric transplants, the 1-year graft survival rates increased from 75.7 percent in 1988 to 87.7 percent in 1996. Transplantation also eliminates the need to be dialyzed three times per week for three to four hours at a time, and the common adverse side effects of dialysis such as fatigue, loss of appetite, and problems with the vascular access site such as infection, clotting, and stenosis. Medicare has paid for a total of 136,000 kidney transplants since 1973, and expects to cover 8,500 this year.

Congress, in 1978, established the ESRD Network Organizations Program to provide coordination and guidance, and assure effective and efficient administration of the Medicare renal disease benefits. ESRD Network responsibilities include:

- Promoting criteria and standards for quality and appropriateness of care;
- Encouraging the use of treatment settings that are compatible with patients' successful rehabilitation;
- Receiving, evaluating, and resolving grievances involving ESRD patient care and/or services; and
- Establishing a Network Council and Medical Review Board to represent area dialysis facilities.

This program was recodified in 1986 when Congress redefined ESRD Network areas. Funding for the ESRD Networks comes from withholding 50 cents per patient per dialysis treatment from payments to dialysis facilities. There are currently 18 ESRD Network Organization areas, and fiscal 2000 ESRD Network funding is \$17 million.

We regularly communicate with and visit ESRD Networks to monitor and assist them in their duties. They submit formal reports to us quarterly, and we conduct annual conferences with the Forum of ESRD Networks to discuss their activities and issues. We now have new contracts with these Networks, which become effective July 1, 2000, that are designed to help us promote a more uniform process for oversight and reporting of Network activities across regions.

The ESRD Network Organizations provide a collegial approach to helping ESRD care providers, with a focus on education to improve quality. State survey agencies also play a critical role in quality assurance and improvement by conducting inspections to verify that minimum quality and performance standards are being met.

### ***Improving Quality***

Improving the quality of care delivered to ESRD beneficiaries is a high priority for us. Beginning in 1994, we took a leadership role in developing clinical indicators to assess the quality of care for dialysis patients. Through the ESRD Networks, we collect measurements each year that indicate the quality of clinical care provided on a national sample of dialysis patients. These measures, which focus on issues such as the adequacy of dialysis and anemia management, indicate whether patients are receiving appropriate care.

The data on these measures are detailed in an annual report that we disseminate to all dialysis providers in order to help them identify opportunities for improvement. Using this national sampling approach, we have been able to document improvement every year since 1994 in the number of dialysis patients receiving appropriate care.

We now are working to learn the rate at which each individual dialysis center is providing appropriate care. By next year, we plan to collect these measures on all patients from all providers. This will enable

us to assess each facility's care, help each facility address any specific weaknesses it may have, and share findings with the public. We are developing a system for dialysis facilities to collect and report these data electronically, and expect to begin testing this electronic system later this year.

We also are getting ready to begin using 16 additional clinical performance measures, as mandated by the Balanced Budget Act (BBA) of 1997. These measures have been developed and were pilot tested last year by ESRD Networks using a national sample of dialysis patients. They will be collected this year, both on a national sample of patients for quality improvement purposes, and on a patients from a sample of dialysis facilities, through the electronic reporting system that we are testing.

In another quality improvement initiative, the National Anemia Cooperative Project, our ESRD Networks have worked with dialysis providers to improve the management of anemia in dialysis patients. Its goals were to decrease the proportion of patients with dangerously low hematocrit levels (less than 31 percent), and to educate dialysis providers on how to use quality improvement techniques. The project involved development of tools such as a quality improvement project guide book and an algorithm for determining appropriate steps in anemia treatment. Between 1996, when the project was implemented nationally, and 1998, the percentage of patients with hematocrit levels greater than 30 increased from 72 percent to 83 percent.

### ***Guarding Hemodialyzer Safety***

A key area where we want to foster further improvement is in the reuse of hemodialyzers. This long-standing practice is specifically addressed in our current conditions of coverage for dialysis centers, which mandate compliance with comprehensive guidelines issued by the Association for the Advancement of Medical Instrumentation. These extensive guidelines address aspects of safe hemodialyzer reuse, such as personnel training, infection control, and equipment maintenance. The guidelines specifically state that, "A decision to reprocess hemodialyzers should be made by a physician knowledgeable about reprocessing and its medical and economic implications," and they mandate that patients be fully informed about reuse of dialyzers.

Because this is such a critical patient safety issue, we plan to propose that each dialysis facility be required to incorporate its reuse program into its overall quality assurance and performance improvement program. We also believe additional funding for enforcement surveys and for Network quality improvement initiatives would help to ensure the industry remains in compliance with the guidelines.

### ***Strengthening Conditions of Coverage***

Revising our conditions of coverage for dialysis centers is a key part of our plans to further strengthen our ability to improve the quality of ESRD care. Dialysis centers must meet these conditions in order to bill Medicare and Medicaid.

We are trying to accomplish several things in the new conditions. We want to:

- Encourage the dialysis industry to work toward continuous quality improvement through systems change;
- Monitor and improve patients' entire experience with dialysis;
- Implement the BBA requirement to monitor the quality of care in dialysis facilities;
- Capitalize on recent improvements in data collection and reporting that we developed in cooperation with the ESRD Networks;

- Incorporate clinical advances created by the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative on adequacy, nutrition, vascular access, anemia, etc.; and
- Incorporate the latest advances in infection control from the Centers for Disease Control.

The proposed conditions would:

- Require facilities to collect and report the performance measures discussed above, and other measures which may include data on patient satisfaction;
- Establish minimum performance standards for clinical outcomes such as adequacy of dialysis, nutritional status, and anemia management, and require facilities that fail to meet these minimum criteria to take corrective actions;
- Hold facilities' governing bodies accountable for developing and monitoring data-driven quality assessment and improvement programs designed to ensure that quality issues are addressed prospectively, rather than waiting for problems to develop and be detected before addressing them; and
- Increase the emphasis on specific health and safety standards, such as water quality and infection control.

We expect to publish these proposed new conditions of coverage next year, and will then accept and consider public comments before issuing a final regulation.

### ***Improving Network and State Surveyor Accountability***

We are working to improve the performance and accountability of ESRD Networks and state survey agencies. For ESRD Networks, we want to develop performance-based contracts, which tie contract renewal, as well as bonus payments, to how well the Network does in meeting specific targets. For ESRD Networks, these targets would likely focus on use of standardized performance data to improve the overall clinical performance of dialysis facilities, use of complaints as a quality safeguard, and ensuring that poor performers meet minimum standards of care.

Meanwhile, we have made several improvements to the ESRD survey process. The survey process and manuals have been revised to focus on the critical safety and health areas in a dialysis facility, i.e., infection control, water quality, reuse of hemodialyzers and other dialysis supplies, and the physical environment in the facility. The basic and advanced surveyor training for State agency surveyors has been improved and standardized.

To further improve the State survey process, we are developing facility-specific profiles to help State survey agencies focus their limited budget dollars. These reports will profile dialysis centers by a variety of measures that indicate whether a facility may have quality problems and warrants a closer look. These profiles are being pilot tested in seven states this summer and we hope to make them available nationwide by next year.

We also want to increase on-site oversight of State surveyor activities by exploring the possibility of conducting more observational surveys in which our staff or a contractor accompany State surveyors during their inspections to assess their effectiveness. We also want to increase the effectiveness and efficiency of State surveyors by providing them with more data which they can use to foster quality improvement. We are revising the guidelines that State survey agencies use to reinforce the accountability of dialysis facility medical directors for patient care. We will explore greater use of the Internet to publish survey results. And we will provide more information to the public about State survey agencies.

And, as mentioned above, we want to decrease the time between surveys of dialysis facilities, from every six years to every three years, so we can better monitor the quality of care. To do so, the President's fiscal 2001 budget would increase funding for surveys from \$2.2 million to \$6.3 million. We believe this would be money well spent, with a direct impact on the quality of patient care.

### ***Improving Beneficiary Information***

As mentioned above, we are planning to share with the public the information that we will be gathering about the quality of care provided at each dialysis facility. We will do so through a new Internet site that, like our Nursing Home Compare website, will help consumers make informed decisions when seeking care. We plan to preview the site later this year with data we now have available to us, such as the type of treatments offered at each facility, the number of hemodialysis stations, the percentage of patients who receive adequate dialysis, the percentage whose anemia has been corrected, and the actual versus expected patient survival rate. We will add additional information as it becomes available to us and as we ensure that appropriate privacy concerns are addressed.

We also want to increase consumer awareness of the role and activities of ESRD Networks and State survey agencies. We will do so through the new Internet site, a new information packet for patients, and brochures for distribution at dialysis facilities, health fairs, and other sites.

Meanwhile, last year we updated our ESRD beneficiary brochure which stresses the importance of receiving adequate dialysis treatments and what patients can do to improve their adequacy measures. It has been distributed to all dialysis facilities and patients and can be found on our [www.medicare.gov](http://www.medicare.gov) website.

### ***Improving Responses to Complaints***

We are working to improve responses to beneficiary complaints about ESRD facilities. We agree that the eight elements identified by the HHS Inspector General for an effective complaint system -- accessibility, objectivity, investigative capacity, timeliness, responsiveness, enforcement authority and follow-up, improvement orientation, and public accountability -- are essential.

We have a workgroup examining how to ensure that all of these are addressed as we strengthen the complaint resolution process and alternative dispute resolution processes that now exist. Our goal is to make the system easier and more responsive to patients, and more manageable and integrated for ESRD Networks and State survey agencies.

We have already developed a system for Network reporting of standardized complaint information that is the first step toward an electronic system for reporting and tracking responses to complaints. We will develop pilot projects to explore ways in which ESRD Networks and State surveyors can better integrate their responses to complaints, and we will establish guidelines for building a more cooperative relationship between Networks and States. We also want to strengthen procedures for anonymous complaints to address the potential for retaliation against patients.

### ***Expanding Beneficiary Options***

To further increase options for ESRD beneficiaries, we are conducting a demonstration project involving Medicare+Choice HMOs. Current law bars ESRD beneficiaries from enrolling in Medicare+Choice plans, although they may remain in one if they develop ESRD after enrollment. As of 1998 there were some 18,500 ESRD beneficiaries in Medicare+Choice plans, and studies show that their dialysis care,

access to transplantation, and mortality rates were no different than for fee-for-service beneficiaries.

Our demonstration, being done with three HMOs (Kaiser-Permanente in Southern California, Health Options in South Florida, and Xantus Healthcare), is testing:

- Year-round open enrollment for ESRD beneficiaries;
- Adjusting payment for age, treatment status (dialysis, transplant episode, or functioning graft) and morbidity; and
- Extra benefits uniquely of interest to the ESRD patient.

This test is expected to conclude in September 2001, with independent evaluation due by June 2002. However, since plans do provide comparable care for ESRD beneficiaries, the Administration would support legislation to remove the restriction on enrollment now.

## **CONCLUSION**

We have made substantial improvements in the care provided to Medicare ESRD beneficiaries, and are committed to making further strides. We believe we can do so by focusing on the patient's entire experience with dialysis and creating a culture of continuous quality improvement throughout the dialysis community. Expanding and improving the information available to consumers on the quality of care in dialysis centers should also help to foster renewed attention to providing high quality service that meets beneficiary needs. Strengthening the role of ESRD Networks and State survey agencies, especially by securing funds for more frequent surveys as proposed in the President's budget, is critical. And increasing payments to reflect increasing costs and patient acuity, as the President is proposing, is also essential to ensure high quality. I thank you again for holding this hearing, and I am happy to answer your questions.